ATTACHMENT 7
MRI SUBSTUDY PROTOCOL

Revised: 14 August, 2000

Core Gel Study MRI Substudy Protocol
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Introduction:

Breast implants may not last a lifetime. While the silicone material itself has not been shown to biodegrade, the shell may rupture due to wear and tear, or direct injury. If the implant shell is ruptured, the escaping gel is usually contained by the scar envelope in the surgical pocket (intracapsular) and may be undetectable. If the scar envelope is torn, the gel can be driven into the local tissue planes and breast tissue (extracapsular).

A dependable estimate of implant failure is essential information to obtain for the benefit of manufacturers, regulatory agencies, plastic surgeons, and past and prospective patients. Several studies with surgical correlation have been published in peer reviewed journals demonstrating that Magnetic Resonance Imaging (MRI) is considered the superior imaging modality to detect silent rupture.

The chemical composition of most medical grade silicones is dimethyl polysiloxane with varying degrees of polymerization. The MR signal is derived from the protons of the methyl groups. The implant shell is also composed of silicone but differs from the gel because of the many additional cross linkages between the methyl groups that result in an elastic solid, therefore only minimal MR signal is produced from the silicone shell because of these cross linkages.

The method of evaluating implants by MRI is to make the silicone appear bright and everything else on the image appears dark, so that the implant shell (which is seen as a dark line) can be seen clearly against the bright silicone background. Intracapsular rupture is detected by seeing the collapsed implant shell (curvilinear low signal intensity lines-linguini signs) surrounded by high signal silicone gel. Soft tissue silicone is detected by seeing high signal silicone against a background of decreased signal soft tissues.

The selection of pulse sequences used to image breast images is determined by the Lamour frequencies and T1 and T2 properties of the tissues (fat, muscle, and silicone). T1 and T2 relaxation is an intrinsic property of each biological tissue. Since the frequency of silicone is close to fat, when chemical suppression techniques (fat or water suppression) are used, the MR signal from silicone behaves similar to fat.

Standard MRI sequences used to image breast implants are a sagittal T2 weighted fast spine echo (FSE) with water suppression and an axial T2 weighted fast spin echo (FSE). The heavily T2 weighted images with a TE of approximately 200, decreases the signal from the breast adipose tissue while keeping the signal from the silicone fairly high. These sequences can vary slightly on different manufacturers' machines and at different institutions, but the principles are the same.

Study Objective:
To determine the incidence and prevalence of silicone gel rupture, using standardized MRI based protocol.

Patient Population:
A subset of 405 women participating in the Mentor Core Gel Protocol who have been selected by random number generation

Scanning Intervals:
This subset of patients will undergo MRI scans of the breast at 1, 2, 4, 6, 8 and 10 years after the original implant surgery.

Study Design:
MRI centers located in close proximity to the investigative sites will be chosen. These centers must have at a minimum: a 1.5 Tesla magnet and a dedicated breast coil. Hardcopies of the imaging sequences, which will include the patient study number, will be made and sent to a central reading center, where the scans will be read by a recognized expert in breast MRI. The results will be entered into the study database. The information that will be collected will include location of the implant and any evidence of intracapsular or extracapsular rupture. The scan will be read locally, as well and a copy of the report will be placed in the patient's permanent medical record.

References

1. Gorczyca DP, Sinha S, Ahn CY, DeBruhl ND, Hayes MK, Gausche VR, Shaw WW, Basset LW, "Silicone Breast Implants in Vivo: MR Imaging. Radiology 1992, 185:407-410.
2. Ahn CY, Shaw WW, Narayanna K, Gorczycz DP, Sinha S, DeBruhl ND. Bassett LW: Definitive Diagnosis of Breast Implant Rupture Using MRI", Plastic and Reconstructive Surgery, September 1993.
3. Gorczyca DP, DeBruhl ND, Ahn CY, Hoyt A, Sayre JW, Nudell P, McCombs M, Shaw WW, Bassette LW, "Silicone Breast Implant Ruptures in an Animal Model: Comparison of Mammography, MRI, US, and CT, Radiology 1994: 190:227-232.
4. Ahn, CY, DeBruhl ND, Gorczyca DP, Shaw WW, Bassett LW, "Comparative Silicone Breast Implant Evaluation using Mammography, Sonography, and Magnetic Resonance Imaging: Experience with 59 Implants", Plastic and Reconstructive Surgery 1994: 94(5):620-627.

MRI Imaging Sequences for the Mentor Protocol "Study of the Safety and Effectiveness of the Mentor Round Gel-filled Mammary Prosthesis in Patients who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision"

The following scanning sequences are the minimal sequences required for the study. Each site may perform additional sequences that are routine at their institution.

- Patients should be scanned 1 year, 2 years, 4 years, 6 years, 8 years and 10 years after the initial implantation.
- Sequences should be acquired using a 1.5 Tesla magnet.
- Patient should be in the prone position in a dedicated bilateral breast coil.
- Make 1 additional hardcopy for Mentor.
- Scan time will be approximately 20 minutes.
- Include patient study ID on hardcopy.
- Mail hardcopies to the following address:

  Mentor Clinical Programs
  Attention: Core Gel breast Monitor
  Mentor Corp.
  201 Mentor Drive
  Santa Barbara, CA 93111

- Scout sagittal sequence – GRASS or other fast sequence (does not have to be hard copy imaged)
- Axial T2 weighted FSE
  - TR/TE 5000/200
  - Matrix 256 x 256
  - NEX 2
  - FOV 32 to 36 depending on patient size
  - Slice thickness 3 skip 1
- Sagittal T2 FSE with water suppression
  - TR/TE 5000/200
  - Matrix 256 x 256
  - NEX 2
  - FOV 18 to 24 depending on patient size
  - Slice thickness 3 skip 1

MRI Substudy Glossary

For purposes of this clinical study, the following basic definitions for interpreting clinical study MRI scans have been standardized:

Intracapsular Implant Rupture (silent rupture): rupture of the implant shell (elastomer envelope) allowing a release of silicone gel, which does not extend beyond the intact fibrous capsule. This is the most common type of implant rupture.

Extracapsular Implant Rupture: rupture of both the implant shell and the fibrous capsule with silicone leakage extending into the surrounding tissue.

Uncollapsed Implant Rupture: when a ruptured implant shell does not collapse or only partially collapses.

Silicone Gel Bleed: Gel bleed occurs in all silicone implants. The most widely accepted definition is microscopic silicone diffusion through an intact implant shell, which does not constitute device rupture.

ATTACHMENT 8
STUDY DEFINTIONS

Study Definitions

1. **Abscess:** A localized collection of pus usually caused by bacterial infection, in or around the breast tissue.

2. **Adverse Events:** An adverse event is defined as any undesirable clinical occurrence in a subject whether it is considered to be device related or not (Clinical Investigation of Medical Devices for Human Subjects - EN 540:1993).

    - Device leaks, tears, or ruptures and all instances of surgical removal of implant for those reasons
    - Removal of the implant for any reason.
    - Baker III or Baker IV capsular contracture, hematoma, seroma, delayed wound healing, necrosis, breast pain, new diagnosis of breast cancer, lactation difficulties, ptosis, irritation/inflammation, assymetry, hypertrophic scarring, lymphadenopathy, extrusion, wrinkling, calcification, nipple/breast sensitivity change, silicone granuloma, fluid accumulation, infection and any secondary surgical procedures.
    - Implant change due to cosmetic dissatisfaction.
    - Any secondary surgical procedure.
    - Examples of secondary procedures that would not be considered adverse events are nipple tattoo, staged reconstruction or port removal.

3. **ALS (amyotrophic lateral sclerosis):** Syndrome marked by muscular weakness and atrophy due to degeneration of motor neurons of the spinal cord, medulla, and cortex.

4. **Asymmetry** is one or more of the following conditions:

    - One cup size difference in breast size
    - Need to differentially pad one cup to fill bra to match the opposite breast size
    - More than 1.5cm difference of nipples as measured laterally from sternal midline and/or clavicular prominences
    - More than 1.5 cm differences in inframmary folds height.
    - Asymmetry due to chest wall deformity such as scoliosis or other deformities of the thoracic cage and/or associated visible differences in shoulder height.

5. **Breast Pain not associated with another complication:** Any post surgical breast pain that is not associated with capsular contraction, infection, abscess or other complication.

6. **Cancer:** A malignant tumor or neoplasm.

7. **Calcification**: Grossly visible calcification on the capsule walls.

8. **Congenital Deformity:** Includes, but is not limited to asymmetry, scoliosis, thoracic cage asymmetry, breast aplasia, hypomastia, deformity due to tumors (hemangiomas, lymphangiomas, giant fibroadenomas), tubular breasts, pectus excavatum or pectus carinatum

9. **Capsular Contracture**: Formation of scar tissue around the implant that tightens or squeezes the implant which can result in excessive firmness of the implanted breast.

10. **Capsulotomy, Open**: Technique used to correct or reduce capsular contracture through surgical intervention by incision into the breast; usually performed when the contracture is moderate; generally limited to replacement of the implant without surgical dissection of the capsule.

11. **Capsulectomy**: Technique used to correct or reduce capsular contracture, through surgical intervention, by incision into the breast; usually performed as a result of a firm, thick capsule marked contracture; generally requires surgical dissection of the capsule prior to replacement of the implant.

12. **Delayed wound healing**: Any incision that shows wound separation.

13. **Hypertrophic Scarring:** Any scar that is not flattened and mature at 18 months or that requires treatment with steroid injections or silicone pads, etc.

14. **Extrusion:** Any exposure of the implant.

15. **Granuloma:** Any foreign body (silicone) that is palpable or visible or seen at surgery.

16. **Hematoma**: Any blood collection large enough to require removal.

17. **Hypoplastic:** Characterized by incomplete or underdevelopment of the breast.

18. **Immediate Breast Reconstruction:** Implant may be inserted up to 1-week post mastectomy.

19. **Infection:** Any bacterial invasion that has systemic or regional signs and symptoms that require antibiotics for treatment (not prophylaxis).

20. **Migration:** Movement of the implant from desired position within or outside the original pocket.

21. **Multiple Sclerosis**: A chronic, slowly progressive disease of the central nervous system characterized by deveopment of disseminated demyelinated glial patches called plaques.

22. **Necrosis:** Tissue death

23. **Pectus Carinatum:** Congenital convex chest wall deformity with abnormalities of the sternum and anterior ribs

24. **Pectus Excavatum:** Congenital concave chest wall deformity with abnormalities of the sternum and anterior ribs.

25. **Ptosis:** Standard grading of ptosis by nipple level.

26. **Secondary Procedure:** Any surgery on the breast taking place after the initial implant surgery. All subsequent surgeries on the breast are considered adverse events EXCEPT: staged reconstruction, port removal, and nipple tattoo. Examples of secondary procedures considered to be adverse events are: surgical capsular contracture intervention or explants.

26. **Serious Unanticipated Adverse Event:** Any other adverse occurrence, side effect, injury, toxicity, or sensitivity reaction that reasonably suggests adverse events from the implant which involve death, life threatening conditions or permanent impairment of body function which have not been addressed in the product literature or which has been addressed, but is occurring with unexpected severity or frequency. These include rheumatologic conditions.

27. **Seroma (fluid accumulation):** Sufficient peri-prosthetic fluid to cause a noticeable volume change or be considered abnormal when detected by breast imaging.

28. Severity of Adverse Events: mild – noticed by patient; moderate – noted by both patient and doctor; severe - requires treatment/intervention.

29. **Wrinkling:** Any detectable implant wrinkle, either visually or palpably.

ATTACHMENT 9
STUDY DEVICES

Sizes, Catalog Number, Diameter, and Projection for Siltex® Round Low Bleed Gel-filled Mammary Prosthesis, Moderate Profile

Device Volume	Catalog Number	Diameter	Projection
100 cc	354-1007G	8.8 cm	2.5 cm
125 cc	354-1257G	9.3 cm	2.8 cm
150 cc	354-1507G	10.2 cm	2.7 cm
175 cc	354-1757G	10.7 cm	2.8 cm
200 cc	354-2007G	11.2 cm	2.8 cm
225 cc	354-2257G	11.4 cm	3.0 cm
250 cc	354-2507G	11.5 cm	3.3 cm
275 cc	354-2757G	12.4 cm	3.4 cm
300 cc	354-3007G	12.6 cm	3.5 cm
325 cc	354-3257G	12.9 cm	3.6 cm
350 cc	354-3507G	13.4 cm	3.7 cm
375 cc	354-3757G	13.4 cm	3.8 cm
400 cc	354-4007G	13.5 cm	3.9 cm
450 cc	354-4507G	13.9 cm	4.1 cm
500 cc	354-5007G	14.2 cm	4.3 cm
550 cc	354-5507G	14.8 cm	4.4 cm
600 cc	354-6007G	15.4 cm	4.5 cm
700 cc	354-7007G	16.8 cm	4.3 cm
800 cc	354-8007G	17.2 cm	4.6 cm

Sizes, Catalog Number, Diameter, and Projection for Smooth Round Low Bleed Gel-filled Mammary Prosthesis, Moderate Profile

Device Volume	Catalog Number	Diameter	Projection
100 cc	350-7100BCG	9.3 cm	2.1 cm
125 cc	350-7125BCG	10.0 cm	2.2 cm
150 cc	350-7150BCG	10.3 cm	2.3 cm
175 cc	350-7175BCG	11.2 cm	2.4 cm
200 cc	350-7200BCG	11.7 cm	2.5 cm
225 cc	350-7225BCG	12.2 cm	2.6 cm
250 cc	350-7250BCG	12.3 cm	2.8 cm
275 cc	350-7275BCG	13.2 cm	2.9 cm
300 cc	350-7300BCG	13.5 cm	3.0 cm
325 cc	350-7325BCG	13.9 cm	3.0 cm
350 cc	350-7350BCG	14.2 cm	3.1 cm
375 cc	350-7375BCG	14.4 cm	3.2 cm
400 cc	350-7400BCG	14.5 cm	3.2 cm
450 cc	350-7450BCG	14.9 cm	3.4 cm
500 cc	350-7500BCG	15.2 cm	3.6 cm
550 cc	350-7550BCG	15.9 cm	3.6 cm
600 cc	350-7600BCG	16.5 cm	3.7 cm
700 cc	350-7700BCG	17.4 cm	3.9 cm
800 cc	350-7800BCG	18.2 cm	4.1 cm

ATTACHMENT 10
CASE REPORT FORMS

The data collected at years 2, 3, 4, 5, 6, 7, 8, 9, and 10 are identical to those collected at 1 year, and hence are not included in this attachment.

MENTOR

Protocol Number
10-009-0799-01

Core Study of the Safety and Effectiveness of the Mentor Round Gel-filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation or Primary Breast Reconstruction or Revision

(Core Gel Breast IDE Clinical Trial)

Site Number	Patient Number	Patient Initials
		first middle last

8/15/00

Instructions for Completing Baseline CRF Packet for Mentor Core Gel Breast IDE Clinical Trial

This package contains the Baseline CRFs (pages 1–25), which should be completed as the patient progresses through the screening period. As you complete the Baseline CRFs, remember these important points:

1. Complete Baseline CRFs with Patient's initials.
   a. Please try to obtain Patient's middle initial.
   b. If Patient has no middle initial, use "–".

2. Leave Patient Number blank on every page until Patient is enrolled.

3. If Patient is enrolled:
   a. Write the Patient Number on every page of the Baseline CRFs.
   b. Place Baseline CRFs in Patient's CRF binder (behind the tabbed divider).

4. If Patient is not enrolled:
   Discard the Baseline CRFs.

5. Do not leave any questions unanswered or blank.

6. Correct entries by drawing a single line through the data and initialing and dating the correction.

7. Always sign and date the forms where indicated.

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE		
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:

PATIENT INITIALS: first | middle | last

Visit Date: month / day / year

INCLUSION CRITERIA

*If any answer to questions 1–4 is **NO**, the patient must be excluded from the study.*

		NO (1)	YES (2)
1.	Is the patient a genetic female 18 years or older?	☐	☐
2	Is the patient a candidate for ***primary* breast augmentation** or ***primary* reconstruction** (for cancer, trauma, surgical loss of breast or congenital deformity) or **revision surgery** (previous augmentation or reconstruction with silicone-filled or saline-filled implants)?	☐	☐
3	Has the patient agreed to follow the procedures for explant analysis?	☐	☐
4	Has the patient agreed to comply with follow-up procedures, including returning for all follow-up visits?	☐	☐

Date Informed Consent signed: month / day / year

EXCLUSION CRITERIA

*If any answer to questions 1–14 is **YES**, the patient must be excluded from the study.*

		N/A	NO (1)	YES (2)
1.	Is the patient pregnant or a nursing mother?		☐	☐
2	Has the patient nursed a child within 3 months of study enrollment?		☐	☐
3.	Has the patient been implanted with any other silicone implant (e g. silicone artificial joints or facial implants)?		☐	☐
4.	Does the patient have a confirmed diagnosis of the following rheumatic diseases or syndromes: systemic lupus erythematosus, Sjogren's syndrome, scleroderma, polymyositis, any other connective tissue disorder, rheumatoid arthritis, crystalline arthritis, infectious arthritis, spondyarthropathies, any other inflammatory arthritic condition, osteoarthritis, fibromyalgia, chronic fatigue syndrome, or any other mechanical or degenerative non-inflammatory rheumatic condition?		☐	☐
5	Does the patient have any condition that would inhibit wound healing? (N/A for reconstruction patient)	☐	☐	☐
6	Does the patient have a diagnosis of active cancer of any type? (N/A for reconstruction patient)	☐	☐	☐
7	Does the patient have an infection or abscess anywhere in the body?		☐	☐
8	Does the patient demonstrate tissue characteristics, which are clinically incompatible with implant (e.g. tissue damage resulting from radiation, inadequate tissue, or compromised vascularity)?		☐	☐
9	Does the patient possess any condition, or is the patient under treatment for any condition, which, in the opinion of the investigator and/or consulting physician(s), may constitute an unwarranted surgical risk?		☐	☐
10	Does the patient have any anatomic or physiologic abnormality, which could lead to significant postoperative complications?		☐	☐
11	Does the patient demonstrate characteristics, such as inappropriate attitude or motivation, which, in the opinion of the investigator, are unreasonable/unrealistic with the risks involved with the surgical procedure?		☐	☐
12	Does the patient have premalignant disease without a subcutaneous mastectomy?		☐	☐
13	Does the patient have untreated or inappropriately treated breast malignancy, without mastectomy?		☐	☐
14.	Does the patient have any implanted metal or metal devices, history of claustrophobia or other condition that would make a MRI scan prohibitive?		☐	☐

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

DEMOGRAPHICS

DATE OF BIRTH: ___ ___ ___ ___ ___ ___ (month / day / year)

GENDER
1 ☑ Female

MARITAL STATUS
1 ☐ Single
2 ☐ Married
3 ☐ Separated
4 ☐ Divorced
5 ☐ Widowed

EDUCATIONAL LEVEL
1 ☐ Less than 12 years
2 ☐ High School Graduate
3 ☐ Some College
4 ☐ College Graduate
5 ☐ Post Graduate

ETHNICITY
1 ☐ African American
2 ☐ Asian
3 ☐ Caucasian
4 ☐ Other _____

ANNUAL HOUSEHOLD INCOME LEVEL
1 ☐ $0 - $20,000
2 ☐ $20,000 - $40,000
3 ☐ $40,000 - $60,000
4 ☐ above $60,000

MEDICAL HISTORY

☐ Check here if no medical history
or
Complete below.

	Absent (1)	Present (2)	Year of Onset or UNK	If PRESENT, please comment
Cardiovascular Disease	☐	☐		
Pulmonary Disease	☐	☐		
Neurological Disease	☐	☐		
Musculoskeletal Disease	☐	☐		
Dermatological Disease	☐	☐		
Lymphatic Disease	☐	☐		
Genitourinary Disease	☐	☐		
Gastrointestinal Disease	☐	☐		
Endocrine Disease	☐	☐		
Allergies, specify _____	☐	☐		
Prior Surgeries, specify _____	☐	☐		
Other, specify. _____	☐	☐		
Other, specify: _____	☐	☐		
Other, specify: _____	☐	☐		

Has the patient ever had any lactation complications?
1 ☐ No
2 ☐ Yes, list: _____

HABITS

Smoking History:
1 ☐ Never smoked
2 ☐ Currently smokes. ___ packs per day
3 ☐ Quit smoking in: ___ ___ ___ ___ year

Current Alcohol Use:
1 ☐ No
2 ☐ Yes: ___ drinks per week

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

INDICATION FOR SURGERY - RIGHT BREAST

0 ☐ Not to be Implanted with Study Device (no current implant)
1 ☐ Not to be Implanted with Study Device (has current implant)

Indicate the primary reason for study device implantation surgery by checking the appropriate boxes for this breast:

2 ☐ **AUGMENTATION, Primary Reason for augmentation:**
- 1 ☐ Post-lactational Mammary Involution
- 2 ☐ General Breast Enlargement
- 3 ☐ Ptosis
- 5 ☐ Augmentation to contralateral breast for post-reconstruction symmetry
- 6 ☐ Other, specify. _____

3 ☐ **RECONSTRUCTION, Primary Reason for reconstruction:**
- 1 ☐ Total-mastectomy—Immediate*
- 2 ☐ Total-mastectomy—Delayed*
- 3 ☐ Subtotal Mastectomy (lumpectomy, quadrantectomy)*

Mastectomy/Surgery Date:
month ___ day ___ year ___

(complete the Breast Cancer History page)

- 4 ☐ Post-trauma
- 5 ☐ Mastopexy to correct contralateral breast for post-reconstruction symmetry
- 6 ☐ Congenital deformity, check one:
  - 1 ☐ Asymmetry *(see Protocol for definition)*
  - 2 ☐ Breast aplasia
  - 3 ☐ Deformity due to tumors (hemangiomas, lymphangiomas, giant fibroadenomas)
  - 4 ☐ Hypomastia
  - 5 ☐ Pectus Carinatum
  - 6 ☐ Pectus Excavatum
  - 7 ☐ Poland's Syndrome
  - 8 ☐ Scoliosis
  - 9 ☐ Spinal curvature
  - 10 ☐ Thoracic cage assymmetry
  - 11 ☐ Tubular breasts
  - 12 ☐ Other: _____

Flap used in reconstruction?
- 1 ☐ No
- 2 ☐ Yes, indicate type:
  - 1 ☐ TRAM
  - 2 ☐ Latissimus dorsi
  - 3 ☐ Other: _____

Tissue expander in place prior to implantation?
- 1 ☐ No
- 2 ☐ Yes, date of placement:

month ___ day ___ year ___

4 ☐ **REVISION, specify type of revision:**
- 1 ☐ Reconstruction revision *(if original reconstruction due to breast cancer surgery, complete the Breast Cancer History page)*
- 2 ☐ Augmentation revision

Original Implant Date: month ___ year ___

Primary Reason for current revision (check one):
- 1 ☐ Capsular Contracture
- 2 ☐ Distortion
- 3 ☐ Extrusion
- 4 ☐ Malposition
- 5 ☐ Post-op Hematoma
- 6 ☐ Post-op Infection
- 7 ☐ Ptosis
- 8 ☐ Rupture
- 9 ☐ Size Change-Down
- 10 ☐ Size Change-Up
- 11 ☐ Valve Retrieval
- 12 ☐ Other: _____

Type of implant being exchanged:
- 1 ☐ Gel
- 2 ☐ Saline
- 3 ☐ Unknown

Number of previous revisions: ___

For **each** previous revision, specify below:

First Revision:

Type of Implant Removed:
- 1 ☐ Gel
- 2 ☐ Saline
- 3 ☐ Unknown

Revision Date: month ___ year ___

Reason for Revision: _____

Second Revision

Type of Implant Removed:
- 1 ☐ Gel
- 2 ☐ Saline
- 3 ☐ Unknown

Revision Date: month ___ year ___

Reason for Revision: _____

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

INDICATION FOR SURGERY - LEFT BREAST

0 ☐ Not to be Implanted with Study Device (no current implant)
1 ☐ Not to be Implanted with Study Device (has current implant)

Indicate the primary reason for study device implantation surgery by checking the appropriate boxes for this breast:

2 ☐ **AUGMENTATION, Primary Reason for augmentation:**
- 1 ☐ Post-lactational Mammary Involution
- 2 ☐ General Breast Enlargement
- 3 ☐ Ptosis
- 5 ☐ Augmentation to contralateral breast for post-reconstruction symmetry
- 6 ☐ Other, specify: _____

3 ☐ **RECONSTRUCTION, Primary Reason for reconstruction:**
- 1 ☐ Total-mastectomy—Immediate*
- 2 ☐ Total-mastectomy—Delayed*
- 3 ☐ Subtotal Mastectomy (lumpectomy, quadrantectomy)*

Mastectomy/Surgery Date: ☐☐ (month) ☐☐ (day) ☐☐☐☐ (year)

(complete the Breast Cancer History page)

- 4 ☐ Post-trauma
- 5 ☐ Mastopexy to correct contralateral breast for post-reconstruction symmetry
- 6 ☐ Congenital deformity, check one:
  - 1 ☐ Asymmetry *(see Protocol for definition)*
  - 2 ☐ Breast aplasia
  - 3 ☐ Deformity due to tumors (hemangiomas, lymphangiomas, giant fibroadenomas)
  - 4 ☐ Hypomastia
  - 5 ☐ Pectus Carinatum
  - 6 ☐ Pectus Excavatum
  - 7 ☐ Poland's Syndrome
  - 8 ☐ Scoliosis
  - 9 ☐ Spinal curvature
  - 10 ☐ Thoracic cage assymmetry
  - 11 ☐ Tubular breasts
  - 12 ☐ Other _____

Flap used in reconstruction?
- 1 ☐ No
- 2 ☐ Yes, indicate type:
  - 1 ☐ TRAM
  - 2 ☐ Latissimus dorsi
  - 3 ☐ Other. _____

Tissue expander in place prior to implantation?
- 1 ☐ No
- 2 ☐ Yes, date of placement.

☐☐ (month) ☐☐ (day) ☐☐☐☐ (year)

4 ☐ **REVISION, specify type of revision:**
- 1 ☐ Reconstruction revision *(if original reconstruction due to breast cancer surgery, complete the Breast Cancer History page)*
- 2 ☐ Augmentation revision

Original Implant Date: ☐☐ (month) ☐☐☐☐ (year)

Primary Reason for current revision (check one):
- 1 ☐ Capsular Contracture
- 2 ☐ Distortion
- 3 ☐ Extrusion
- 4 ☐ Malposition
- 5 ☐ Post-op Hematoma
- 6 ☐ Post-op Infection
- 7 ☐ Ptosis
- 8 ☐ Rupture
- 9 ☐ Size Change-Down
- 10 ☐ Size Change-Up
- 11 ☐ Valve Retrieval
- 12 ☐ Other: _____

Type of implant being exchanged:
- 1 ☐ Gel
- 2 ☐ Saline
- 3 ☐ Unknown

Number of previous revisions: ☐

For **each** previous revision, specify below:

First Revision:

Type of implant removed:
- 1 ☐ Gel
- 2 ☐ Saline
- 3 ☐ Unknown

Revision Date: ☐☐ (month) ☐☐☐☐ (year)

Reason for Revision: _____

Second Revision

Type of implant removed:
- 1 ☐ Gel
- 2 ☐ Saline
- 3 ☐ Unknown

Revision Date: ☐☐ (month) ☐☐☐☐ (year)

Reason for Revision _____

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

BREAST CANCER HISTORY

☐ N/A ***(never diagnosed with breast cancer in either breast)***

RIGHT BREAST ☐ N/A (never diagnosed with breast cancer)

1 Date of Diagnosis: ____ (month) ____ (year)

2 Location.
- ☐ Upper Medial
- ☐ Upper Lateral
- ☐ Lower Medial
- ☐ Lower Lateral

3 Staging.
1. ☐ Stage Tis *(In situ)*
2. ☐ Stage X *(cannot stage)*
3. ☐ Stage I
4. ☐ Stage II
5. ☐ Stage IIIA
6. ☐ Stage IIIB
7. ☐ Stage IV

4. Pathology

a Histologic type:
1. ☐ Cancer, Not Otherwise Specified
2. ☐ Ductal
3. ☐ Lobular
4. ☐ Nipple
5. ☐ Other, specify: _____

b Differentiation:
1. ☐ Poor (G3–G4)
2. ☐ Moderate (G2)
3. ☐ Well (G1)
4. ☐ Cannot be assessed (GX)

c. Estrogen receptor:
1. ☐ Positive
2. ☐ Negative

d. Progesterone receptor:
1. ☐ Positive
2. ☐ Negative

LEFT BREAST ☐ N/A (never diagnosed with breast cancer)

1. Date of Diagnosis: ____ (month) ____ (year)

2. Quadrant:
- ☐ Upper Medial
- ☐ Upper Lateral
- ☐ Lower Medial
- ☐ Lower Lateral

3 Staging.
1. ☐ Stage Tis *(In situ)*
2. ☐ Stage X *(cannot stage)*
3. ☐ Stage I
4. ☐ Stage II
5. ☐ Stage IIIA
6. ☐ Stage IIIB
7. ☐ Stage IV

4. Pathology

a Histologic type:
1. ☐ Cancer, Not Otherwise Specified
2. ☐ Ductal
3. ☐ Lobular
4. ☐ Nipple
5. ☐ Other, specify: _____

b Differentiation
1. ☐ Poor (G3–G4)
2. ☐ Moderate (G2)
3. ☐ Well (G1)
4. ☐ Cannot be assessed (GX)

c Estrogen receptor:
1. ☐ Positive
2. ☐ Negative

d Progesterone receptor.
1. ☐ Positive
2. ☐ Negative

Referring Oncologist

Name: _____

Address: _____

_____

Phone:(_____) _____

BREAST CANCER TREATMENT HISTORY ☐ N/A (never treated for breast cancer)

Type of Adjunctive Therapy·

a Radiation·
- 1 ☐ No
- 2 ☐ Yes

b Chemotherapy:
- 1 ☐ No
- 2 ☐ Yes, specify drug names:

1. _____
2. _____
3 _____
4. _____

c. Hormonal therapy:
- 1 ☐ No
- 2 ☐ Yes, check all that apply·
  - ☐ Hormones
  - ☐ Endocrine surgery
  - ☐ Endocrine radiation
  - ☐ Recommended, unknown if administered

d Biological response modifier therapy:
- 1 ☐ No
- 2 ☐ Yes, specify types: _____
- 3 ☐ Recommended, unknown if administered

e. Other breast cancer-directed therapy·
- 1 ☐ No
- 2 ☐ Yes, specify types: _____
- 3 ☐ Recommended, unknown if administered

MENTOR	Core Gel Breast IDE Clinical Trial		BASELINE		
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

If rheumatologist has examined the patient and reports that the patient has any of the following, then patient is excluded from the study.

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following?

RHEUMATIC DISEASE	NO	YES	Has disease been diagnosed in a blood relative? NO	YES	UNKNOWN
Connective Tissue Disorders: SLE	☐	☐	☐	☐	☐
Sjogren's Syndrome	☐	☐	☐	☐	☐
Scleroderma	☐	☐	☐	☐	☐
Polymyositis	☐	☐	☐	☐	☐
Other Connective Tissue Disorders	☐	☐	☐	☐	☐
Inflammatory Arthritis: Rheumatoid Arthritis	☐	☐	☐	☐	☐
Crystalline Arthritis	☐	☐	☐	☐	☐
Infectious Arthritis	☐	☐	☐	☐	☐
Spondyarthropathies	☐	☐	☐	☐	☐
Other Inflammatory Arthritis	☐	☐	☐	☐	☐
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	☐	☐	☐	☐	☐
Fibromyalgia	☐	☐	☐	☐	☐
Chronic Fatigue	☐	☐	☐	☐	☐
Other Mechanical or Degenerative	☐	☐	☐	☐	☐

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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RHEUMATOLOGY SYMPTOMS ☐ No symptoms present

Please check any **current** symptoms which:

1 The patient experiences on a regular basis

2 The cause is unknown and cannot be attributed to any patient activity

RHEUMATOLOGICAL SYSTEMS REVIEW	YES	DATE OF ONSET (if known) month	year	RHEUMATOLOGICAL SYSTEMS REVIEW	YES	DATE OF ONSET (if known) month	year
Loss of weight without dieting	☐			Numbness of hands	☐		
Fatigue	☐			Jaw pain	☐		
Insomnia	☐			Open sores	☐		
Weakness	☐			Redness of eyes	☐		
Exhaustion	☐			Dryness of mouth	☐		
Joint swelling	☐			Back pain/stiffness	☐		
Heel pain	☐			Severe chest pains	☐		
Frequent muscle cramps	☐			Chronic cough	☐		
Numbness of feet	☐			Difficulty swallowing	☐		
Ringing in ears	☐			Frequent, severe or persistent diarrhea or constipation	☐		
Pain/grittiness in eyes	☐			Severe rashes	☐		
Dryness of eyes, nose	☐			Frequent muscle cramps	☐		
Pain on swallowing or chewing	☐			Severe dryness of skin	☐		
Neck pain/stiffness	☐			Tender lumps/bumps	☐		
Pain on breathing	☐			Excessive sensitivity to sun	☐		
Heart murmurs	☐			Color changes on hands or feet with cold exposure	☐		
Loss of appetite	☐			Joint pain	☐		
Persistent fever	☐			Frequent hives	☐		
Night sweats	☐			Numbness of hands	☐		
Generalized aching	☐			Tightness of skin	☐		
Loss of height	☐			Unusual hair loss	☐		
Joint pain	☐			Tenderness of scalp	☐		
Frequent muscle pain	☐			Severe bruising with little or no injury	☐		

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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RHEUMATOLOGICAL PHYSICAL EXAMINATION

☐ No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	PRESENT AND OUTSIDE NORMAL LIMITS	PHYSICAL FINDING	PRESENT AND OUTSIDE NORMAL LIMITS	POSSIBLE INDICATION
Muscle weakness. Headlift from supine position against gravity	☐	Hair loss	☐	*Lupus, Scleroderma*
Inability to raise arms	☐	Skin tightness, especially face and hands	☐	*Scleroderma*
Inability to get out of chair	☐	Raynaud's phenomenon	☐	*Lupus, Scleroderma*
Joint swellings: Wrists	☐	Calcinosis over tibia, ulna, elbows	☐	*Scleroderma, Dermatomyositis*
Digits	☐	Swollen digits	☐	*Juvenile RA Reiter's syndrome Psoriatic arthritis Early scleroderma Reflex sympathetic dystrophy*
Elbows	☐	Erythema over knuckles	☐	*Dermatomyositis*
Knees	☐	Bluish hue color on eyelids	☐	*Dermatomyositis*
Ankles	☐	Non-tender lumps or nodules on elbows	☐	*Rheumatoid gout*
Joint deformities and flexion contracture: Boutonniére[1]	☐	Tender lumps-tibia	☐	*Erythema nodosum*
Ulnar drift[2]	☐	Painless eye redness	☐	*Conjunctivitis*
Swan neck[3]	☐	Painful eye redness with decreased vision, small pupils	☐	*Uveitis*
Trigger fingers	☐	Tenderness—insertion of deltoids	☐	*Polymyalgia rheumatica*
Joint tenderness	☐	Muscle tenderness	☐	*Polymyositis*
Grip strength and motion-finger to palm crease (normal = 0 cm)	☐	Nail pittings	☐	*Psoriatic arthritis, Reiter's syndrome*
Neck motion–chin to chest or sternum (normal = 0 cm)	☐	Tinels or Phalen's signs	☐	*Carpal tunnel syndrome*
Chest expansion (normal = at least 5 cm)	☐	Skin rashes	☐	*Discoid lupus*
Occiput to wall (normal = 0 cm)	☐			
Jaw motion (normally upper-lower incisors 3 cm)	☐			
Back motion-measure 10 cm above posterior supine iliac spines-with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	☐			

[1] ***Boutonniére*** - *Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension*

[2] ***Ulnar Drift*** - *Joint change at the metacarpophalangeal joints Long axis of fingers deviate in an ulnar direction*

[3] ***Swan Neck*** - *Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility*

1 Does the patient require an exam by a rheumatologist?
- ☐ No
- ☐ Yes

Rheumatologist's Name: _____

2. If yes, rheumatologist's findings:
- ☐ Presence of rheumatic disease **Patient is excluded.**
- ☐ No indication of rheumatic disease

MENTOR	Core Gel Breast IDE Clinical Trial		BASELINE		
PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS (first middle last)
	10-009	0 0 1			

PHYSICAL EXAMINATION

HEIGHT (in)	WEIGHT (lb)
___.___	___.___

Check the appropriate box for each body system indicated.

ND = Not Done N = Normal A = Abnormal, comment is required

	ND	N	A	COMMENT **ONLY** IF ABNORMAL
HEENT	☐	☐	☐	
Cardiovascular	☐	☐	☐	
Pulmonary	☐	☐	☐	
Neurological	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Dermatological	☐	☐	☐	
Lymphatic	☐	☐	☐	
Genitourinary	☐	☐	☐	
Gastrointestinal	☐	☐	☐	

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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BREAST EXAM HISTORY

Number of Pregnancies. ___ *(if none, enter "00")*

Complications? 1 ☐ No
2 ☐ Yes, number of complications: ___

Number of Live Births: ___ *(if none, enter "00")*

Breastfeeding? 1 ☐ No
2 ☐ Yes, was there adequate milk? 1 ☐ No
2 ☐ Yes, Number of Breastfed Children: ___ *(if none, enter "00")*

Age of Menarche: ___

Age of Menopause: ___ 0 ☐ N/A

Family History of Breast Cancer? 1 ☐ No
2 ☐ Yes

History of Fibrocystic Disease? 1 ☐ No
2 ☐ Yes

PREVIOUS BREAST SURGERY (excluding mastectomy)

RIGHT 0 ☐ None
Number of Previous Surgeries: ___
List most recent:
Surgery Type: _____
Reason. _____
Date: ___ (month) ___ (year)

LEFT 0 ☐ None
Number of Previous Surgeries. ___
List most recent:
Surgery Type: _____
Reason: _____
Date: ___ (month) ___ (year)

BREAST BIOPSY

RIGHT 0 ☐ None
List most recent:
Biopsy Type. _____
Reason: _____
Date: ___ (month) ___ (year)
Result. 1 ☐ Negative
2 ☐ Positive

LEFT 0 ☐ None
List most recent:
Biopsy Type: _____
Reason: _____
Date: ___ (month) ___ (year)
Result: 1 ☐ Negative
2 ☐ Positive

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

BREAST MEASUREMENTS

RIGHT 0 ☐ Not to be Implanted with Study Device

Circumferential Breast Measurement ___ cm

Bra Size (i e 32A) ___ ☐ N/A (breast absent)

LEFT 0 ☐ Not to be Implanted with Study Device

Circumferential Breast Measurement ___ cm

Bra Size (i.e. 32A) ___ ☐ N/A (breast absent)

NIPPLE/BREAST SENSITIVITY - How would patient describe the feeling in nipple(s) and/or breast(s) now?

RIGHT 0 ☐ Not to be Implanted with Study Device

Nipple Sensation is:
1 ☐ Unacceptably low
2 ☐ Acceptable
3 ☐ Unacceptably high
4 ☐ N/A, nipple absent

Breast sensation is:
1 ☐ Unacceptably low
2 ☐ Acceptable
3 ☐ Unacceptably high
4 ☐ N/A, breast absent

LEFT 0 ☐ Not to be Implanted with Study Device

Nipple Sensation is:
1 ☐ Unacceptably low
2 ☐ Acceptable
3 ☐ Unacceptably high
4 ☐ N/A, nipple absent

Breast sensation is:
1 ☐ Unacceptably low
2 ☐ Acceptable
3 ☐ Unacceptably high
4 ☐ N/A, breast absent

MAMMOGRAPHY RESULTS

Date of Most Recent Mammogram: ___ (month) ___ (year) 0 ☐ Not Done

RIGHT

1 ☐ Birads 0 *Needs additional imaging evaluation*
2 ☐ Birads 1 *Negative*
3 ☐ Birads 2 *Benign finding*
4 ☐ Birads 3 *Probable benign finding—short interval follow-up is suggested*
5 ☐ Birads 4 *Suspicious abnormality—biopsy should be considered*
6 ☐ Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*

List abnormality: _____

LEFT

1 ☐ Birads 0 *Needs additional imaging evaluation*
2 ☐ Birads 1 *Negative*
3 ☐ Birads 2 *Benign finding*
4 ☐ Birads 3 *Probable benign finding—short interval follow-up is suggested*
5 ☐ Birads 4 *Suspicious abnormality—biopsy should be considered*
6 ☐ Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*

List abnormality: _____

INVESTIGATOR SIGNATURE

I have reviewed the Baseline Case Report Forms and have verified that all data are accurate

_____ ___ (month) ___ (day) ___ (year)

Investigator's Signature

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	☐	☐	☐	☐
2. I feel that I have a number of good qualities.	☐	☐	☐	☐
3. All in all, I am inclined to feel that I am a failure.	☐	☐	☐	☐
4. I am able to do things as well as most people.	☐	☐	☐	☐
5. I feel I do not have much of which to be proud.	☐	☐	☐	☐
6 I take a positive attitude towards myself.	☐	☐	☐	☐
7. On the whole, I am satisfied with myself.	☐	☐	☐	☐
8. I wish I could have more respect for myself.	☐	☐	☐	☐
9. I certainly feel useless at times.	☐	☐	☐	☐
10. At times I think I am no good at all.	☐	☐	☐	☐

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself ***to yourself.*** Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a ***circle*** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

*Remember, put a **circle** around the response number you have chosen for each statement.*	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

*Remember, put a **circle** around the response number you have chosen for each statement.*	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25 I am a hateful person.	1	2	3	4	5
26 I am losing my mind.	1	2	3	4	5
27 I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29 I feel that my family doesn't trust me.	1	2	3	4	5
30 I am popular with women.	1	2	3	4	5
31 I am mad at the whole world.	1	2	3	4	5
32 I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35 I am neither too fat nor too thin.	1	2	3	4	5
36 I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

*Remember, put a **circle** around the response number you have chosen for each statement.*	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51 Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52 I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54 I should have more sex appeal.	1	2	3	4	5
55 I am as religious as I want to be.	1	2	3	4	5
56 I wish I could be more trustworthy.	1	2	3	4	5
57 I shouldn't tell so many lies.	1	2	3	4	5
58 I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60 I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. *(Use past tense if parents are not living.)*	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71 I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)

*Remember, put a **circle** around the response number you have chosen for each statement.*	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77 I do things without thinking about them first.	1	2	3	4	5
78 I try to play fair with my friends and family.	1	2	3	4	5
79 I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. *(Use past tense if parents are not living.)*	1	2	3	4	5
81 I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86 I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

	Excellent	Very Good	Good	Fair	Poor
1. In general, would you say your health is: (Circle **one** number)	1	2	3	4	5

	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
2. Compared to one year ago, how would you rate your health in general **now?** (Circle **one** number)	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much? (Circle **one** number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing **several** flights of stairs	1	2	3
Climbing **one** flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking **more than a mile**	1	2	3
Walking **several blocks**	1	2	3
Walking **one block**	1	2	3
Bathing or dressing yourself	1	2	3

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
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SF-36 (Page 2 of 3)

4. During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?** (Circle **one** number for each question.)	YES	NO
Cut down on the **amount of time** you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the **kind** of work or other activities	1	2
Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? (Circle **one** number for each question.)	YES	NO
Cut down on the **amount of time** you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as **carefully** as usual	1	2

6. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle **one** number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much **bodily** pain have you had during the **past 4 weeks?** (Circle **one** number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)? (Circle **one** number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the **past 4 weeks...**	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle **one** number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How **TRUE** or **FALSE** is **each** of the following statements for you? (Circle **one** number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS: first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body,*** using the following scale:

1 = Have strong negative feelings
2 = Have moderate negative feelings
3 = Have no feeling one way or the other
4 = Have moderate positive feelings
5 = Have strong positive feelings

☐	1. Body Scent	☐	19. Arms
☐	2. Appetite	☐	20. Chest
☐	3. Nose	☐	21. Appearance of Eyes
☐	4. Physical Stamina	☐	22. Cheeks/Cheekbones
☐	5. Reflexes	☐	23. Hips
☐	6. Lips	☐	24. Legs
☐	7. Muscular Strength	☐	25. Physique
☐	8. Waist	☐	26. Sex Drive
☐	9. Energy Level	☐	27. Feet
☐	10. Thighs	☐	28. Sex Organs
☐	11. Ears	☐	29. Appearance of Stomach
☐	12. Biceps	☐	30. Health
☐	13. Chin	☐	31. Sex Activities
☐	14. Body Build	☐	32. Body Hair
☐	15. Physical Coordination	☐	33. Physical Condition
☐	16. Buttocks	☐	34. Face
☐	17. Agility	☐	35. Weight
☐	18. Width of Shoulders		

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

☐ N/A **(not a cancer patient)**

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

☐ N/A **(not a cancer patient)**

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past 2 months.

1 2 3 4 5 6 7

No Hardship — Tremendous Hardship

9. Rate how often you feel discouraged about your life.

1 2 3 4 5 6 7

Always — Never

10. Rate your satisfaction with your work and your jobs around the house in the past month.

1 2 3 4 5 6 7

Very Dissatisfied — Very Satisfied

11. How uncomfortable do you feel today?

1 2 3 4 5 6 7

Not at All — Very Uncomfortable

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past 2 weeks.

1 2 3 4 5 6 7

Totally Disruptive — No Disruption

13. How much is pain or discomfort interfering with your daily activities?

1 2 3 4 5 6 7

Not at All — A Great Deal

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past 2 weeks.

1 2 3 4 5 6 7

Tremendous Hardship — No Hardship

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

☐ N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1 2 3 4 5 6 7

All None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1 2 3 4 5 6 7

Unwilling Very Willing

17. How much nausea have you had in the past 2 weeks?

1 2 3 4 5 6 7

None A Great Deal

18. Rate the degree to which you are frightened of the future.

1 2 3 4 5 6 7

Constantly Terrified Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1 2 3 4 5 6 7

Unwilling Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1 2 3 4 5 6 7

None All

21. Rate your confidence in your prescribed course of treatment.

1 2 3 4 5 6 7

No Confidence Very Confident

22. How well do you appear today?

1 2 3 4 5 6 7

Extremely Poor Extremely Well

MENTOR	Core Gel Breast IDE Clinical Trial	BASELINE			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

PREVIOUS AND CONCOMITANT MEDICATIONS

Please record all medications taken within 30 days prior to Baseline Visit (include non-prescription drugs such as herbs, vitamins, etc) and all medications taken during the preoperative period through the end of the Operative Visit

DRUG NAME	INDICATION	START DATE month	day	year	STOP DATE (if continuing, circle "C") month	day	year	
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C

MENTOR	Core Gel Breast IDE Clinical Trial	OPERATIVE REPORT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

SURGICAL INFORMATION

Date of Surgery: ___ ___ (month) ___ ___ (day) ___ ___ ___ ___ (year)

Institution at which surgery took place: _____

Anesthesia Type (check all that apply):
- ☐ General
- ☐ Local
- ☐ Local with Sedation
- ☐ Other, specify: _____

Were any other surgical procedures performed at this time?
1. ☐ No
2. ☐ Yes, specify: _____

	RIGHT ☐ Not Implanted With Study Device	LEFT ☐ Not Implanted With Study Device
Device Placement.	1 ☐ Submuscular 2 ☐ Subglandular 3 ☐ Subpectoral 4 ☐ Other: _____	1 ☐ Submuscular 2 ☐ Subglandular 3 ☐ Subpectoral 4 ☐ Other: _____
Incision Size.	___ ___ ___ cm	___ ___ ___ cm
Implant Information:	1 ☐ Smooth Surface 2 ☐ Textured Surface Device Volume. ___ ___ ___ cc	1 ☐ Smooth Surface 2 ☐ Textured Surface Device Volume. ___ ___ ___ cc
Catalog Number:		
Lot Number:		
Surgical Approach:	1 ☐ Periareolar 2 ☐ Inframammary 3 ☐ Transaxillary 4 ☐ Mastectomy Scar 5 ☐ Other: _____	1 ☐ Periareolar 2 ☐ Inframammary 3 ☐ Transaxillary 4 ☐ Mastectomy Scar 5 ☐ Other: _____
Pocket Irrigation (check all that apply):	☐ Saline Only ☐ Steroid: _____ Dose: _____ ☐ Antibiotic _____ ☐ Drug: _____ ☐ Other. _____	☐ Saline Only ☐ Steroid: _____ Dose: _____ ☐ Antibiotic: _____ ☐ Drug. _____ ☐ Other: _____
Post-Operative Recommendations (check all that apply):	☐ Antibiotic. _____ ☐ Restricted Activities ☐ Recommend Massage ☐ Other _____	☐ Antibiotic: _____ ☐ Restricted Activities ☐ Recommend Massage ☐ Other: _____

Complete Adverse Events Report if the patient experienced any operative complications or adverse events.

MENTOR	Core Gel Breast IDE Clinical Trial	OPERATIVE REPORT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

SURGEON'S ASSESSMENT

Check one:

RIGHT

0 ☐ N/A (not implanted with study device)
1 ☐ Satisfied
2 ☐ Dissatisfied, specify: _____

_____

LEFT

0 ☐ N/A (not implanted with study device)
1 ☐ Satisfied
2 ☐ Dissatisfied, specify: _____

_____

_____ ___ ___ ____
Surgeon's Signature month day year

MENTOR	Core Gel Breast IDE Clinical Trial	PATIENT REGISTRY FORM *Please type or **legibly** print **all requested information.***			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

I. DEVICE INFORMATION

Implantation Date: ___ ___ ___ ___ ___ ___ ___ ___
month day year

RIGHT SIDE	LEFT SIDE
Product Name. _____	Product Name: _____
Cat. No _____	Cat No.. _____
Lot No.: _____	Lot No.: _____

II. PATIENT INFORMATION

Patient Name: _____ Phone No : (_____) _____
Last First MI Area Code

Address. _____
Street Address City State Zip Code Country

Date of Birth: ___ ___ ___ ___ ___ ___ ___ ___
month day year

Social Security No.. ___ ___ - ___ ___ - ___ ___ ___ ___

III. IMPLANTING SURGEON INFORMATION

Name. _____ Phone No.. (_____) _____
Last First MI Area Code

Address: _____
Street Address City State Zip Code Country

Name of facility where surgery was performed: _____

MENTOR	Core Gel Breast IDE Clinical Trial	6 MONTH VISIT			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

Visit Date ___ ___ ___ (month day year) 0 ☐ Missed Visit

BREAST MEASUREMENTS

RIGHT 0 ☐ Not Implanted with Study Device

Circumferential Breast Measurement ___ cm

Bra Size (i.e. 32A) ___ ☐ N/A (breast absent)

LEFT 0 ☐ Not Implanted with Study Device

Circumferential Breast Measurement ___ cm

Bra Size (i.e. 32A) ___ ☐ N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram ___ ___ (month year) 0 ☐ Not Done

RIGHT

1 ☐ Birads 0 *Needs additional imaging evaluation*
2 ☐ Birads 1 *Negative*
3 ☐ Birads 2 *Benign finding*
4 ☐ Birads 3 *Probable benign finding—short interval follow-up is suggested*
5 ☐ Birads 4 *Suspicious abnormality—biopsy should be considered*
6 ☐ Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
List abnormality. _____

LEFT

1 ☐ Birads 0 *Needs additional imaging evaluation*
2 ☐ Birads 1 *Negative*
3 ☐ Birads 2 *Benign finding*
4 ☐ Birads 3 *Probable benign finding—short interval follow-up is suggested*
5 ☐ Birads 4 *Suspicious abnormality—biopsy should be considered*
6 ☐ Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
List abnormality. _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?
   1 ☐ No
   2 ☐ Yes, without complications
   3 ☐ Yes, with complications
   Complete Adverse Events Report

2 Has the patient attempted to breastfeed since the last visit?
   1 ☐ No
   2 ☐ Yes, was there adequate milk?
      1 ☐ No ***(Enter code 30 on Adverse Events Report)***
      2 ☐ Yes

3 Would the patient have this breast surgery again?
   1 ☐ No, reason: _____
   2 ☐ Yes

4. **Breast Cancer Reconstruction Patients only:**
   ☐ N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?
   1 ☐ No
   2 ☐ Yes, check all that apply:
      ☐ Radiation Therapy
      ☐ Chemotherapy
      ☐ Other, specify _____

Treating Oncologist

Name _____

Phone (_____) _____

MENTOR	Core Gel Breast IDE Clinical Trial	6 MONTH VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS

Right Prosthesis is:	Left Prosthesis is:
0 ☐ Not Implanted with Study Device	0 ☐ Not Implanted with Study Device
1 ☐ Baker Class I (normally soft and natural appearance)	1 ☐ Baker Class I (normally soft and natural appearance)
2 ☐ Baker Class II (a natural appearance despite palpable firmness)	2 ☐ Baker Class II (a natural appearance despite palpable firmness)
3 ☐ Baker Class III (firm with visible distortion)	3 ☐ Baker Class III (firm with visible distortion)
4 ☐ Baker Class IV (obvious spherical distortion)	4 ☐ Baker Class IV (obvious spherical distortion)

Complete Adverse Events Report for Baker III or IV.

NIPPLE/BREAST SENSITIVITY

How would patient describe the feeling in nipple(s) and/or breast(s) now?

*If unacceptably high or low at baseline, and sensation remains the same post-operatively, do **not** complete an Adverse Events Report.*

If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.

RIGHT	LEFT
0 ☐ Not Implanted with Study Device	0 ☐ Not Implanted with Study Device
Nipple Sensation is:	Nipple Sensation is:
1 ☐ Unacceptably low	1 ☐ Unacceptably low
2 ☐ Acceptable	2 ☐ Acceptable
3 ☐ Unacceptably high	3 ☐ Unacceptably high
4 ☐ N/A, nipple absent	4 ☐ N/A, nipple absent
Breast sensation is:	Breast sensation is:
1 ☐ Unacceptably low	1 ☐ Unacceptably low
2 ☐ Acceptable	2 ☐ Acceptable
3 ☐ Unacceptably high	3 ☐ Unacceptably high
4 ☐ N/A, breast absent	4 ☐ N/A, breast absent

Complete Adverse Events Report for any complications or adverse events noted at this visit.

MENTOR	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS	6 MONTH VISIT

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS (first middle last)	☐ No Adverse Events
	10-009	0 0 1				

Enter **one** adverse event per line If the event was experienced at more than one body site, enter each body site on a separate line

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = **Secondary Procedure** ***(enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)**** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
	☐1 ☐3 ☐2 ☐4	☐0 ☐1 ☐2	☐0 ☐3 ☐1 ☐2		☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 ____ days, Date. __/__/____ ☐ 2 _____ ☐ 5 _____ ☐ 3 Procedure Type Code†:____ Procedure Date: ____/____/____	☐1 ☐4 ☐2 ☐3	
	☐1 ☐3 ☐2 ☐4	☐0 ☐1 ☐2	☐0 ☐3 ☐1 ☐2		☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 ____ days, Date __/__/____ ☐ 2 _____ ☐ 5 _____ ☐ 3 Procedure Type Code†:____ Procedure Date ____/____/____	☐1 ☐4 ☐2 ☐3	

_____ Investigator's Signature

month ____ day ____ year ____

Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.

***ADVERSE EVENT CODES**

1 = Asymmetry
2 = Baker II Capsular Contracture **with** Surgical Intervention
3 = Baker III Capsular Contracture
4 = Baker IV Capsular Contracture
5 = Breast pain not associated with any other complication
6 = Breast—Unacceptably Low Sensitivity
7 = Breast—Unacceptably High Sensitivity
8 = Calcification
9 = Delayed Wound Healing
10 = Extrusion
11 = Granuloma
12 = Hematoma
13 = Hypertrophic Scarring
14 = Infection
15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify _____
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
28 = Lactation Difficulties, specify _____
29 = Other, specify _____
30 = Other, specify _____

†SECONDARY PROCEDURE TYPE CODES

81 = Biopsy
82 = Capsulectomy
83 = Explantation with Replacement**
84 = Explantation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify _____
92 = Other, specify _____

MENTOR	Core Gel Breast IDE Clinical Trial	6 MONTH VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

CONCOMITANT MEDICATIONS

Please record all medications (include non-prescription drugs such as herbs, vitamins, etc.) taken since the last visit.

DRUG NAME	INDICATION	START DATE month	day	year	STOP DATE (if continuing, circle "C") month	day	year	
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C

MENTOR	Core Gel Breast IDE Clinical Trial	6 MONTH VISIT			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

CONCOMITANT SURGERIES

Please record all surgeries that are **not related to breast implant surgeries** (e.g , liposuction, face lift, gall bladder resection, etc.) that have occurred since the last visit.

Do **not** record secondary procedures related to adverse events or breast implants here 0 ☐ None

TYPE OF SURGERY	INDICATION	DATE OF SURGERY month	day	year

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

Visit Date: ___ ___ (month) ___ ___ (day) ___ ___ ___ ___ (year) 0 ☐ Missed Visit

BREAST MEASUREMENTS

RIGHT 0 ☐ Not Implanted with Study Device

Circumferential Breast Measurement ___ ___ cm

Bra Size (i.e 32A) ___ ___ ___ ___ ☐ N/A (breast absent)

LEFT 0 ☐ Not Implanted with Study Device

Circumferential Breast Measurement ___ ___ cm

Bra Size (i.e 32A) ___ ___ ___ ___ ☐ N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram: ___ ___ (month) ___ ___ ___ ___ (year) 0 ☐ Not Done

RIGHT

1 ☐ Birads 0 *Needs additional imaging evaluation*
2 ☐ Birads 1 *Negative*
3 ☐ Birads 2 *Benign finding*
4 ☐ Birads 3 *Probable benign finding—short interval follow-up is suggested*
5 ☐ Birads 4 *Suspicious abnormality—biopsy should be considered*
6 ☐ Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
List abnormality: _____

LEFT

1 ☐ Birads 0 *Needs additional imaging evaluation*
2 ☐ Birads 1 *Negative*
3 ☐ Birads 2 *Benign finding*
4 ☐ Birads 3 *Probable benign finding—short interval follow-up is suggested*
5 ☐ Birads 4 *Suspicious abnormality—biopsy should be considered*
6 ☐ Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
List abnormality. _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?
   1 ☐ No
   2 ☐ Yes, without complications
   3 ☐ Yes, with complications
   Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?
   1 ☐ No
   2 ☐ Yes, was there adequate milk?
      1 ☐ No ***(Enter code 30 on Adverse Events Report)***
      2 ☐ Yes

3. Would the patient have this breast surgery again?
   1 ☐ No, reason. _____
   2 ☐ Yes

4. **Breast Cancer Reconstruction Patients only:**
   ☐ N/A (augmentation patient)

   Has the patient received any adjuvant therapies since the last visit?
   1 ☐ No
   2 ☐ Yes, check all that apply:
      ☐ Radiation Therapy
      ☐ Chemotherapy
      ☐ Other, specify: _____

   Treating Oncologist

   Name: _____

   Phone (_____) _____

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS

Right Prosthesis is:	Left Prosthesis is
0 ☐ Not Implanted with Study Device	0 ☐ Not Implanted with Study Device
1 ☐ Baker Class I (normally soft and natural appearance)	1 ☐ Baker Class I (normally soft and natural appearance)
2 ☐ Baker Class II (a natural appearance despite palpable firmness)	2 ☐ Baker Class II (a natural appearance despite palpable firmness)
3 ☐ Baker Class III (firm with visible distortion)	3 ☐ Baker Class III (firm with visible distortion)
4 ☐ Baker Class IV (obvious spherical distortion)	4 ☐ Baker Class IV (obvious spherical distortion)

Complete Adverse Events Report for Baker III or IV.

NIPPLE/BREAST SENSITIVITY

How would patient describe the feeling in nipple(s) and/or breast(s) now?

*If unacceptably high or low at baseline, and sensation remains the same post-operatively, do **not** complete an Adverse Events Report.*

If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report

RIGHT	LEFT
0 ☐ Not Implanted with Study Device	0 ☐ Not Implanted with Study Device
Nipple Sensation is:	Nipple Sensation is:
1 ☐ Unacceptably low	1 ☐ Unacceptably low
2 ☐ Acceptable	2 ☐ Acceptable
3 ☐ Unacceptably high	3 ☐ Unacceptably high
4 ☐ N/A, nipple absent	4 ☐ N/A, nipple absent
Breast sensation is:	Breast sensation is:
1 ☐ Unacceptably low	1 ☐ Unacceptably low
2 ☐ Acceptable	2 ☐ Acceptable
3 ☐ Unacceptably high	3 ☐ Unacceptably high
4 ☐ N/A, breast absent	4 ☐ N/A, breast absent

Complete Adverse Events Report for any complications or adverse events noted at this visit.

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE ☐ No diagnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?**
If YES, complete Adverse Event Report.

RHEUMATIC DISEASE		NO	YES	DATE OF ONSET (if known) month	year
Connective Tissue Disorders:	SLE	☐	☐		
	Sjogren's Syndrome	☐	☐		
	Scleroderma	☐	☐		
	Polymyositis	☐	☐		
	Other Connective Tissue Disorders	☐	☐		
Inflammatory Arthritis:	Rheumatoid Arthritis	☐	☐		
	Crystalline Arthritis	☐	☐		
	Infectious Arthritis	☐	☐		
	Spondyarthropathies	☐	☐		
	Other Inflammatory Arthritis	☐	☐		
Non-Inflammatory Rheumatic Conditions:	Osteoarthritis	☐	☐		
	Fibromyalgia	☐	☐		
	Chronic Fatigue	☐	☐		
	Other Mechanical or Degenerative	☐	☐		
Other, specify: _____		☐	☐		
Other, specify: _____		☐	☐		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis.

Name _____

Address: _____

_____

Phone: (_____) _____

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

RHEUMATOLOGY SYMPTOMS (Page 1 of 2)

1 ☐ No symptoms; patient not referred to rheumatologist

Please check any **current** symptoms which:
1 The patient experiences on a regular basis
2 The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	☐	☐			☐	☐
Fatigue	☐	☐			☐	☐
Insomnia	☐	☐			☐	☐
Weakness	☐	☐			☐	☐
Exhaustion	☐	☐			☐	☐
Joint swelling	☐	☐			☐	☐
Heel pain	☐	☐			☐	☐
Frequent muscle cramps	☐	☐			☐	☐
Numbness of feet	☐	☐			☐	☐
Ringing in ears	☐	☐			☐	☐
Pain/grittiness in eyes	☐	☐			☐	☐
Dryness of eyes, nose	☐	☐			☐	☐
Pain on swallowing or chewing	☐	☐			☐	☐
Neck pain/stiffness	☐	☐			☐	☐
Pain on breathing	☐	☐			☐	☐
Heart murmurs	☐	☐			☐	☐
Loss of appetite	☐	☐			☐	☐
Persistent fever	☐	☐			☐	☐
Night sweats	☐	☐			☐	☐
Generalized aching	☐	☐			☐	☐
Loss of height	☐	☐			☐	☐
Joint pain	☐	☐			☐	☐
Frequent muscle pain	☐	☐			☐	☐

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:
1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	☐	☐			☐	☐
Jaw pain	☐	☐			☐	☐
Open sores	☐	☐			☐	☐
Redness of eyes	☐	☐			☐	☐
Dryness of mouth	☐	☐			☐	☐
Back pain/stiffness	☐	☐			☐	☐
Severe chest pains	☐	☐			☐	☐
Chronic cough	☐	☐			☐	☐
Difficulty swallowing	☐	☐			☐	☐
Frequent, severe or persistent diarrhea or constipation	☐	☐			☐	☐
Severe rashes	☐	☐			☐	☐
Frequent muscle cramps	☐	☐			☐	☐
Severe dryness of skin	☐	☐			☐	☐
Tender lumps/bumps	☐	☐			☐	☐
Excessive sensitivity to sun	☐	☐			☐	☐
Color changes on hands or feet with cold exposure	☐	☐			☐	☐
Joint pain	☐	☐			☐	☐
Frequent hives	☐	☐			☐	☐
Numbness of hands	☐	☐			☐	☐
Tightness of skin	☐	☐			☐	☐
Unusual hair loss	☐	☐			☐	☐
Tenderness of scalp	☐	☐			☐	☐
Severe bruising with little or no injury	☐	☐			☐	☐

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2) ☐ No symptoms present

Check the box for each physical finding noted to be present and outside normal limits

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	☐	☐			☐	☐
Inability to raise arms	☐	☐			☐	☐
Inability to get out of chair	☐	☐			☐	☐
Joint swellings. Wrists	☐	☐			☐	☐
Digits	☐	☐			☐	☐
Elbows	☐	☐			☐	☐
Knees	☐	☐			☐	☐
Ankles	☐	☐			☐	☐
Joint deformities and flexion contracture: Boutonniére[1]	☐	☐			☐	☐
Ulnar drift[2]	☐	☐			☐	☐
Swan neck[3]	☐	☐			☐	☐
Trigger fingers	☐	☐			☐	☐
Joint tenderness	☐	☐			☐	☐
Grip strength and motion-finger to palm crease (normal = 0 cm)	☐	☐			☐	☐
Neck motion–chin to chest or sternum (normal = 0 cm)	☐	☐			☐	☐
Chest expansion (normal = at least 5 cm)	☐	☐			☐	☐
Occiput to wall (normal = 0 cm)	☐	☐			☐	☐
Jaw motion (normally upper-lower incisors 3 cm)	☐	☐			☐	☐
Back motion-measure 10 cm above posterior supine iliac spines-with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	☐	☐			☐	☐

[1] ***Boutonniére*** - *Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension*

[2] ***Ulnar Drift*** - *Joint change at the metacarpophalangeal joints Long axis of fingers deviate in an ulnar direction*

[3] ***Swan Neck*** - *Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility*

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
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RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	*Lupus, Scleroderma*	☐	☐			☐	☐
Skin tightness, especially face and hands	*Scleroderma*	☐	☐			☐	☐
Raynaud's phenomenon	*Lupus, Scleroderma*	☐	☐			☐	☐
Calcinosis over tibia, ulna, elbows	*Scleroderma, Dermatomyositis*	☐	☐			☐	☐
Swollen digits	*Juvenile RA Reiter s syndrome Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy*	☐	☐			☐	☐
Erythema over knuckles	*Dermatomyositis*	☐	☐			☐	☐
Bluish hue color on eyelids	*Dermatomyositis*	☐	☐			☐	☐
Non-tender lumps or nodules on elbows	*Rheumatoid gout*	☐	☐			☐	☐
Tender lumps-tibia	*Erythema nodosum*	☐	☐			☐	☐
Painless eye redness	*Conjunctivitis*	☐	☐			☐	☐
Painful eye redness with decreased vision, small pupils	*Uveitis*	☐	☐			☐	☐
Tenderness—insertion of deltoids	*Polymyalgia rheumatica*	☐	☐			☐	☐
Muscle tenderness	*Polymyositis*	☐	☐			☐	☐
Nail pittings	*Psoriatic arthritis, Reiter's syndrome*	☐	☐			☐	☐
Tinels or Phalen's signs	*Carpal tunnel syndrome*	☐	☐			☐	☐
Skin rashes	*Discoid lupus*	☐	☐			☐	☐

Does the patient require an examination by a rheumatologist?

☐ No

☐ Yes, record rheumatologist's findings:

_____

_____

_____

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	☐	☐	☐	☐
2. I feel that I have a number of good qualities.	☐	☐	☐	☐
3. All in all, I am inclined to feel that I am a failure.	☐	☐	☐	☐
4. I am able to do things as well as most people.	☐	☐	☐	☐
5 I feel I do not have much of which to be proud.	☐	☐	☐	☐
6 I take a positive attitude towards myself.	☐	☐	☐	☐
7. On the whole, I am satisfied with myself.	☐	☐	☐	☐
8. I wish I could have more respect for myself.	☐	☐	☐	☐
9. I certainly feel useless at times.	☐	☐	☐	☐
10. At times I think I am no good at all.	☐	☐	☐	☐

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself ***to yourself.*** Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a ***circle*** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

*Remember, put a **circle** around the response number you have chosen for each statement.*	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1 I have a healthy body.	1	2	3	4	5
2 I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4 I am a decent sort of person.	1	2	3	4	5
5 I am an honest person.	1	2	3	4	5
6 I am a bad person.	1	2	3	4	5
7 I am a cheerful person.	1	2	3	4	5
8 I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10 I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
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TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

*Remember, put a **circle** around the response number you have chosen for each statement.*	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39 I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41 I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44 I am satisfied with my family relationships.	1	2	3	4	5
45 I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47 I am as sociable as I want to be.	1	2	3	4	5
48 I try to please others, but I don't overdo it.	1	2	3	4	5
49 I am no good at all from a social standpoint.	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
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TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

*Remember, put a **circle** around the response number you have chosen for each statement.*	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60 I wish I didn't give up as easily as I do.	1	2	3	4	5
61 I treat my parents as well as I should. *(Use past tense if parents are not living.)*	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64 I am satisfied with the way I treat other people.	1	2	3	4	5
65 I should be more polite to others.	1	2	3	4	5
66 I ought to get along better with other people.	1	2	3	4	5
67 I gossip a little at times.	1	2	3	4	5
68 At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72 I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)

*Remember, put a **circle** around the response number you have chosen for each statement.*	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77 I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79 I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. *(Use past tense if parents are not living.)*	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83 I do not forgive others easily.	1	2	3	4	5
84 I would rather win than lose in a game.	1	2	3	4	5
85 I feel good most of the time.	1	2	3	4	5
86 I do poorly in sports and games.	1	2	3	4	5
87 I am a poor sleeper.	1	2	3	4	5
88 I do what is right most of the time.	1	2	3	4	5
89 I sometimes use unfair means to get ahead.	1	2	3	4	5
90 I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98 I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
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TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

	Excellent	Very Good	Good	Fair	Poor
1. In general, would you say your health is: (Circle **one** number)	1	2	3	4	5

	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
2 Compared to one year ago, how would you rate your health in general **now?** (Circle **one** number)	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much? (Circle **one** number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing **several** flights of stairs	1	2	3
Climbing **one** flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking **more than a mile**	1	2	3
Walking **several blocks**	1	2	3
Walking **one block**	1	2	3
Bathing or dressing yourself	1	2	3

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
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4. During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?** (Circle **one** number for each question.)	YES	NO
Cut down on the **amount of time** you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the **kind** of work or other activities	1	2
Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? (Circle **one** number for each question.)	YES	NO
Cut down on the **amount of time** you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as **carefully** as usual	1	2

6. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle **one** number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much **bodily** pain have you had during the **past 4 weeks?** (Circle **one** number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)? (Circle **one** number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
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9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the **past 4 weeks...**	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle **one** number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How **TRUE** or **FALSE** is **each** of the following statements for you? (Circle **one** number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5

MENTOR	Core Gel Breast IDE Clinical Trial		1 YEAR VISIT		
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body,*** using the following scale:

1 = Have strong negative feelings
2 = Have moderate negative feelings
3 = Have no feeling one way or the other
4 = Have moderate positive feelings
5 = Have strong positive feelings

☐	1. Body Scent	☐	19. Arms
☐	2. Appetite	☐	20. Chest
☐	3. Nose	☐	21. Appearance of Eyes
☐	4. Physical Stamina	☐	22. Cheeks/Cheekbones
☐	5. Reflexes	☐	23. Hips
☐	6. Lips	☐	24. Legs
☐	7. Muscular Strength	☐	25. Physique
☐	8. Waist	☐	26. Sex Drive
☐	9. Energy Level	☐	27. Feet
☐	10. Thighs	☐	28. Sex Organs
☐	11. Ears	☐	29. Appearance of Stomach
☐	12. Biceps	☐	30. Health
☐	13. Chin	☐	31. Sex Activities
☐	14. Body Build	☐	32. Body Hair
☐	15. Physical Coordination	☐	33. Physical Condition
☐	16. Buttocks	☐	34. Face
☐	17. Agility	☐	35. Weight
☐	18. Width of Shoulders		

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

☐ N/A **(not a cancer patient)**

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1 2 3 4 5 6 7

Never Continually

2. How well are you coping with your everyday stress?

1 2 3 4 5 6 7

Not Well Very Well

3. How much time do you spend thinking about your illness?

1 2 3 4 5 6 7

Constantly Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1 2 3 4 5 6 7

Able Unable

5. Has nausea affected your daily functioning?

1 2 3 4 5 6 7

Not At All A Great Deal

6. How well do you feel today?

1 2 3 4 5 6 7

Extremely Poor Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1 2 3 4 5 6 7

Very Able Not Able

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

☐ N/A **(not a cancer patient)**

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past 2 months.

1 2 3 4 5 6 7

No Hardship — Tremendous Hardship

9. Rate how often you feel discouraged about your life.

1 2 3 4 5 6 7

Always — Never

10. Rate your satisfaction with your work and your jobs around the house in the past month.

1 2 3 4 5 6 7

Very Dissatisfied — Very Satisfied

11. How uncomfortable do you feel today?

1 2 3 4 5 6 7

Not at All — Very Uncomfortable

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past 2 weeks.

1 2 3 4 5 6 7

Totally Disruptive — No Disruption

13. How much is pain or discomfort interfering with your daily activities?

1 2 3 4 5 6 7

Not at All — A Great Deal

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past 2 weeks.

1 2 3 4 5 6 7

Tremendous Hardship — No Hardship

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

☐ N/A **(not a cancer patient)**

15. How much of your usual household tasks are you able to complete?

1 2 3 4 5 6 7

All None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1 2 3 4 5 6 7

Unwilling Very Willing

17. How much nausea have you had in the past 2 weeks?

1 2 3 4 5 6 7

None A Great Deal

18. Rate the degree to which you are frightened of the future.

1 2 3 4 5 6 7

Constantly Terrified Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1 2 3 4 5 6 7

Unwilling Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1 2 3 4 5 6 7

None All

21. Rate your confidence in your prescribed course of treatment.

1 2 3 4 5 6 7

No Confidence Very Confident

22. How well do you appear today?

1 2 3 4 5 6 7

Extremely Poor Extremely Well

MENTOR	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS	1 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS (first middle last)	☐ No Adverse Events
	10-009	0 0 1				

Enter **one** adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = **Secondary Procedure** ***(enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)**** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
	☐ 1 ☐ 3 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2	☐ 0 ☐ 3 ☐ 1 ☐ 2		☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 ____ days, Date __/__/____ ☐ 2 _____ ☐ 5 _____ ☐ 3 Procedure Type Code†.___ Procedure Date: ____/____/____	☐ 1 ☐ 4 ☐ 2 ☐ 3	
	☐ 1 ☐ 3 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2	☐ 0 ☐ 3 ☐ 1 ☐ 2		☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 ____ days, Date. __/__/____ ☐ 2 _____ ☐ 5 _____ ☐ 3 Procedure Type Code† ___ Procedure Date ____/____/____	☐ 1 ☐ 4 ☐ 2 ☐ 3	

_____ Investigator's Signature

month ___ day ___ year ____

Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.

***ADVERSE EVENT CODES**

1 = Asymmetry
2 = Baker II Capsular Contracture **with** Surgical Intervention
3 = Baker III Capsular Contracture
4 = Baker IV Capsular Contracture
5 = Breast pain not associated with any other complication
6 = Breast—Unacceptably Low Sensitivity
7 = Breast—Unacceptably High Sensitivity
8 = Calcification
9 = Delayed Wound Healing
10 = Extrusion
11 = Granuloma
12 = Hematoma
13 = Hypertrophic Scarring
14 = Infection
15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify _____
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
28 = Lactation Difficulties, specify _____
29 = Other, specify. _____
30 = Other, specify _____

†SECONDARY PROCEDURE TYPE CODES

81 = Biopsy
82 = Capsulectomy
83 = Explantation with Replacement**
84 = Explantation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify _____
92 = Other, specify _____

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

CONCOMITANT MEDICATIONS

Please record all medications (include non-prescription drugs such as herbs, vitamins, etc.) taken since the last visit.

DRUG NAME	INDICATION	START DATE month	day	year	STOP DATE (if continuing, circle "C") month	day	year	
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C

MENTOR	Core Gel Breast IDE Clinical Trial	1 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

CONCOMITANT SURGERIES

Please record all surgeries that are **not related to breast implant surgeries** (e.g., liposuction, face lift, gall bladder resection, etc.) that have occurred since the last visit.

Do **not** record secondary procedures related to adverse events or breast implants here. 0 ☐ None

TYPE OF SURGERY	INDICATION	DATE OF SURGERY month	day	year

MENTOR	Core Gel Breast IDE Clinical Trial	SECONDARY PROCEDURES REPORT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

SECONDARY PROCEDURES INFORMATION

Surgery Date: ___ ___ ___ (month day year)

Institution at which surgery took place: _____

Anesthesia Type (check all that apply):

- ☐ General
- ☐ Local
- ☐ Local with Sedation
- ☐ Other, specify: _____

Indication for Procedure (check one Primary Reason for each breast):

		RIGHT	LEFT
1	Asymmetry	☐	☐
2.	Breast Pain (Excessive)	☐	☐
3	Capsular Contracture (Baker II)	☐	☐
4.	Capsular Contracture (Baker III)	☐	☐
5	Capsular Contracture (Baker IV)	☐	☐
6	Delayed Wound Healing	☐	☐
7	Extrusion	☐	☐
8	Hematoma	☐	☐
9	Hypertrophic Scarring	☐	☐
10.	Infection	☐	☐
11.	Irritation/Inflammation	☐	☐
12.	Necrosis	☐	☐
13.	Position Change	☐	☐
14.	Ptosis	☐	☐
15.	Rupture	☐	☐
16.	Seroma	☐	☐
17	Size Change	☐	☐
18.	Staged Reconstruction	☐	☐
19.	Wrinkling	☐	☐
20	Other, specify. _____	☐	☐
21.	Other, specify: _____	☐	☐

Type of Secondary Procedure (check all that apply):

		RIGHT	LEFT
1	Biopsy	☐	☐
2	Capsulectomy	☐	☐
3	Implant Size Change ***(complete Re-Implantation Report)***	☐	☐
4	Implant Removal (without replacement)	☐	☐
5	Implant Removal (with replacement other than size change) ***(complete Re-Implantation Report)***	☐	☐
6.	Incision and Drainage	☐	☐
7	Mastopexy	☐	☐
8	Nipple Reconstruction	☐	☐
9.	Nipple Tattoo	☐	☐
10.	Open Capsulotomy	☐	☐
11	Position Change	☐	☐
12	Scar Revision	☐	☐
13.	Skin Adjustment	☐	☐
14	Other, specify: _____	☐	☐

EXPLANTATION REPORT

☐ Not Explanted

1 Explantation Site(s):

- 1 ☐ Right
- 2 ☐ Left
- 3 ☐ Both

2. Will prosthesis(es) be returned to Mentor?

- 1 ☐ No, reason: _____
- 2 ☐ Yes

_____ Surgeon's Signature

___ ___ ___ (month day year)

MENTOR	Core Gel Breast IDE Clinical Trial	RE-IMPLANTATION REPORT (Page 1 of 2)

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS (first middle last)	PROCEDURE DATE (month day year)
	10-009	0 0 1				

RE-IMPLANTATION INFORMATION (for patients receiving a new study implant **only**)

Right Explant Date:
☐ N/A (Not explanted) month day year

Left Explant Date:
☐ N/A (Not explanted) month day year

Reason for Explant/Reimplant (check one):

	RIGHT	LEFT
1. Same as Primary Reason for Secondary Procedure	☐	☐
2. Iatrogenic Damage	☐	☐
3. Rupture Discovered	☐	☐
4 Pocket Size Changed	☐	☐
5. Other, specify: _____	☐	☐

Anesthesia Type (check all that apply):
1 ☐ General 3 ☐ Local with Sedation 2 ☐ Local 4 ☐ Other, specify: _____

Institution at which surgery took place: _____

Intraoperative Parental Medications: ☐ None Given
1. _____ 3 _____
2 _____ 4. _____

	RIGHT ☐ Not Re-implanted with Study Device	LEFT ☐ Not Re-implanted with Study Device
Device Placement:	1 ☐ Submuscular 2 ☐ Subglandular 3 ☐ Subpectoral 4 ☐ Other: _____	1 ☐ Submuscular 2 ☐ Subglandular 3 ☐ Subpectoral 4 ☐ Other: _____
Incision Size:	____ cm	____ cm
Implant Information:	1 ☐ Smooth Surface 2 ☐ Textured Surface	1 ☐ Smooth Surface 2 ☐ Textured Surface
Catalog Number.		
Lot Number:		
Surgical Approach:	1 ☐ Periareolar 2 ☐ Inframammary 3 ☐ Transaxillary 4 ☐ Mastectomy Scar 5 ☐ Other: _____	1 ☐ Periareolar 2 ☐ Inframammary 3 ☐ Transaxillary 4 ☐ Mastectomy Scar 5 ☐ Other. _____
Pocket Irrigation (check all that apply):	☐ Saline Only ☐ Steroid: _____ Dose: _____ ☐ Antibiotic: _____ ☐ Drug: _____ ☐ Other: _____	☐ Saline Only ☐ Steroid: _____ Dose: _____ ☐ Antibiotic: _____ ☐ Drug: _____ ☐ Other: _____
Post-Operative Recommendations (check all that apply):	☐ Antibiotic: _____ ☐ Restricted Activities ☐ Recommend Massage ☐ Other: _____	☐ Antibiotic: _____ ☐ Restricted Activities ☐ Recommend Massage ☐ Other _____

MENTOR	Core Gel Breast IDE Clinical Trial	RE-IMPLANTATION REPORT (Page 2 of 2)			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS: first middle last

SURGEON'S ASSESSMENT

Check one.

RIGHT

0 ☐ N/A (not re-implanted with study device)
1 ☐ Satisfied
2 ☐ Dissatisfied, specify. _____

LEFT

0 ☐ N/A (not re-implanted with study device)
1 ☐ Satisfied
2 ☐ Dissatisfied, specify: _____

Were any technical problems relating to the prosthesis noted during the re-implantation procedure (**not** including complications/ adverse experiences)?

1 ☐ No
2 ☐ Yes, specify: _____

_____

_____ month day year

Surgeon's Signature

Complete Adverse Events Report if the patient experienced any operative complications or adverse events.

MENTOR	Core Gel Breast IDE Clinical Trial	END OF STUDY			
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS first middle last

1 ☐ Patient completed the 10 year study

OR

Patient did not complete study, complete below:

Date of Discontinuation: ___ ___ ___ (month day year)

Reason for Discontinuation (check **one** box only):

2 ☐ Protocol Violation, specify. _____

3 ☐ Prosthesis Explanted, ***complete Adverse Events Report and Secondary Procedures Report***

4 ☐ Consent Withdrawn by Patient, reason: _____

5 ☐ Lost to Follow-up, date of last documented contact. ___ ___ ___ (month day year)

(If patient is continuing in study at another site, this form should not be completed.)

List Contacts: 1 _____

2 _____

3. _____

6 ☐ Death ***(Complete Adverse Events Report)***

Date of Death: ___ ___ ___ (month day year)

Cause: _____

7 ☐ Other, specify: _____

INVESTIGATOR SIGNATURE

I have reviewed **all** Case Report Forms for this patient and have verified that all data are accurate.

_____ ___ ___ ___

Investigator's Signature (month day year)

MENTOR	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS	____ YEAR VISIT

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS (first middle last)
	10-009	0 0 1			

Enter **one** adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	IMPLANT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = **Secondary Procedure** ***(enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)**** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
	☐ 1 ☐ 3 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2	☐ 0 ☐ 3 ☐ 1 ☐ 2		☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 ____ days, Date __/__/____ ☐ 2 _____ ☐ 5 _____ ☐ 3 Procedure Type Code† ____ Procedure Date ____/____/____	☐ 1 ☐ 4 ☐ 2 ☐ 3	
	☐ 1 ☐ 3 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2	☐ 0 ☐ 3 ☐ 1 ☐ 2		☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 ____ days, Date. __/__/____ ☐ 2 _____ ☐ 5 _____ ☐ 3 Procedure Type Code† ____ Procedure Date· ____/____/____	☐ 1 ☐ 4 ☐ 2 ☐ 3	

_____ Investigator's Signature

month day year

***Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.**

***ADVERSE EVENT CODES**

1 = Asymmetry
2 = Baker II Capsular Contracture **with** Surgical Intervention
3 = Baker III Capsular Contracture
4 = Baker IV Capsular Contracture
5 = Breast pain not associated with any other complication
6 = Breast—Unacceptably Low Sensitivity
7 = Breast—Unacceptably High Sensitivity
8 = Calcification
9 = Delayed Wound Healing
10 = Extrusion
11 = Granuloma
12 = Hematoma
13 = Hypertrophic Scarring
14 = Infection
15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify _____
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
28 = Lactation Difficulties, specify· _____
29 = Other, specify _____
30 = Other, specify _____
31 = Other, specify _____
32 = Other, specify· _____
33 = Other, specify _____

†SECONDARY PROCEDURE TYPE CODES

81 = Biopsy
82 = Capsulectomy
83 = Explantation with Replacement**
84 = Explantation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify _____
92 = Other, specify _____
93 = Other, specify _____

MENTOR	Core Gel Breast IDE Clinical Trial	_____ YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS: first middle last

CONCOMITANT MEDICATIONS

Please record all medications (include non-prescription drugs such as herbs, vitamins, etc.) taken since the last visit.

DRUG NAME	INDICATION	START DATE month	day	year	STOP DATE (if continuing, circle "C") month	day	year	
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C
								C

MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS (first middle last)	PATIENT SOCIAL SECURITY NO
	10-009	0 0 1				

MRI EVALUATION

Patient's Date of Birth: ____ ____ ____ (month day year)

MRI Reviewer: _____

Date of MRI Evaluation. ____ ____ ____ (month day year)

Scan Quality (check one):
- 1 ☐ Good
- 2 ☐ Adequate
- 3 ☐ Inadequate

	RIGHT ☐ Not Implanted with Study Device	LEFT ☐ Not Implanted with Study Device
Device Placement:	1 ☐ Submuscular 2 ☐ Subglandular	1 ☐ Submuscular 2 ☐ Subglandular
Implant Type.	1 ☐ Smooth 2 ☐ Siltex	1 ☐ Smooth 2 ☐ Siltex
Implant Evaluation·	1 ☐ No Evidence of Rupture 2 ☐ Indeterminate Evidence of Rupture 3 ☐ Rupture. *Check one Type:* 1 ☐ Intracapsular 2 ☐ Extracapsular *Check one Condition.* 1 ☐ Uncollapsed 2 ☐ Partially Collapsed 3 ☐ Fully Collapsed (linguini sign)	1 ☐ No Evidence of Rupture 2 ☐ Indeterminate Evidence of Rupture 3 ☐ Rupture: *Check one Type:* 1 ☐ Intracapsular 2 ☐ Extracapsular *Check one Condition.* 1 ☐ Uncollapsed 2 ☐ Partially Collapsed 3 ☐ Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 ☐ No Evidence of Extracapsular Silicone 2 ☐ Indeterminate for Extracapsular Silicone 3 ☐ Definite Extracapsular Silicone	1 ☐ No Evidence of Extracapsular Silicone 2 ☐ Indeterminate for Extracapsular Silicone 3 ☐ Definite Extracapsular Silicone

Notes _____

_____

_____

_____ ____ ____ ____
Reviewer's Signature (month day year)

This study was not designed to detect breast cancer, and so the findings and impressions here should not replace routine screening mammography and clinical examination. Some implant ruptures and small amounts of soft tissue silicone below our thresholds for detection may not be seen by this method.

ATTACHMENT 11
CORE GEL RETRIEVAL PLAN

Revised: 14 August, 2000

Mentor Silicone Gel-Filled Mammary Prosthesis
Explanted Device Retrieval Protocol

Objective:

To evaluate explanted silicone gel-filled mammary prostheses from patients enrolled in the Core Gel clinical study and document and catalogue various failure modes. The data will be reviewed to develop test methodology to predict the clinical failure modes.

Background:

As part of the Core Gel study, any patient who reports a rupture requiring their device to be explanted and replaced will be asked permission to evaluate the explanted device. Mentor will initially evaluate the explanted devices in accordance with Complaint and MDR procedures, reference SOP-HS-112 and SOP-HS-113.

The retrieved devices will undergo a visual or "gross" evaluation as well as a microscopic visual evaluation. Photographs are taken of all returned devices. The details of the complaint handling process are specified in the procedures listed in the reference section.

The retrieval protocol outlined is an extension of the existing complaint handling process. However, this retrieval program is designed to be used for explanted devices from patients enrolled in the Core Gel clinical study. When a complaint is reported relative to the Core Gel study, the PE staff will obtain pertinent questions pertaining to the patient history, device, complaint, implant and explant procedures. The FER will be used for all reported complaints (See Attachment 1). The explanted devices will be returned to Mentor utilizing Mentor's existing return kit and decontamination process. The explanted devices will be evaluated visually, and a description of the device failure will be documented in writing, on a diagram as well as photographed according to procedure, DOP-QA-4015.

Sample Size:

Explanted Core Gel clinical study devices that failed primarily due to rupture, and for which Mentor has received patient authorization to perform destructive testing, will be evaluated as part of the retrieval program. A maximum of 1000 patients (2000 devices) will be enrolled in the Core Gel clinical study.

Device retrieval and shipping procedure

The explanted devices will be returned to Mentor using the standard return kit and decontamination process. The PE staff will confirm the address of the complainant and send the Product Return Kit. The materials included within the Product Return Kit are as follows:

- Mailing envelope, 15" x 12" Airborne bubble pack
- Cardboard box, 8 x 8 x 4 corrugated, complies with Federal spec. PPP-B636J stamped "PE Returns"
- Packing Material, 20" x 16 ½" PIG material pad
- Three 9" x 12" self-sealing bags, Part Number 211032-3
- Airborne Express airbill, preprinted
- Envelope that includes all patient medical information and explanted device paperwork is enclosed in the envelope
- Authorization For Return and Examination of Medical Device form
- Authorization For Release of Medical Information (ROMI) form.
- Decontamination Instructions (Attachment 4)

Test Methodology:

Visual testing

Retrieved devices will be handled and evaluated according to DOP-QA-4015. The devices will be visually evaluated with the naked eye as well as microscopically. The observations will be recorded on a data sheet. The location of the tear, pinhole, cut, or other abnormality will be recorded on a diagram and maintained with the complaint file. The visual properties of the gel will also be recorded. Photographs will be taken and maintained with the complaint file.

Physical and Mechanical testing

The device catalog number, lot number, weight and dimensions will be recorded.

Explanted devices will be cut appropriately to perform the dimensional and mechanical shell property testing. Dependent upon the visual observations and conditions of the retrieved device, various tests will be performed on the device in accordance with established Test Methods.

Mechanical testing will consist of the following: tension set (TM 406), ultimate elongation (TM 019) and shell/patch joint strength (TM 401). Additional test methods may be employed to further analyze the defects.

Intact Devices and Chemical testing

Upon notification of a customer, of a bilateral replacement where one device remains intact, PE will request permission to analyze the intact device, specifically the gel filler. If permission is granted, the device will be returned to Mentor for gel cohesion testing (TM 366).

Data Collection:

The following minimum information will be recorded: patient name, physician name, device type, catalog number, lot number, date of implant, date of explant, reported complaint, fill volume at explant, patient history, concomitant medications, and other relevant information that establish the in-vivo conditions. The Field Experience Report (FER) form will be utilized to collect the pertinent medical related information. (Attachment 1)

All in-vivo conditions, visual, mechanical and chemical test results as well as any additional information will be recorded on the attached forms or other established data forms. The data will be entered in a database for analysis.

Data Analysis:

The data will be analyzed by the various test conditions, i.e., visual observations (macroscopic and microscopic), dimensional data, mechanical data, etc. The data will be reviewed for specific trends, e.g., device type, size, shape and clinical variables including years in vivo, implant placement, incision location, and Betadine or other antimicrobial usage. The data will be evaluated to determine if there is any correlation to the time of implant failure. Test data will be periodically analyzed to determine its relevance to failure modes, product design, product use, and to determine if the ongoing collection of retrieval program information is warranted. These data will also be utilized to develop test methodology to predict the clinical failure modes, if applicable.

Reporting requirements:

All data will be recorded on the attached forms or on data sheets relevant to the specific test. The data will be entered into a database and subsequently analyzed. The results will be summarized in a test report and submitted to FDA.

References:

SOP-HS-112, Rev. K	Product Complaint Handling System
SOP-HS-113, Rev. N	Medical Device Reporting (MDR)
DOP-QA-4002, Rev. E	Product Evaluation: Processing of a Complaint File

DOP-QA-4004, Rev. B	Product Evaluation Coding System
DOP-QA-4007, Rev. D	Product Complaint Handling by the Calling Coordinators
DOP-QA-4015, Rev. D	Product Evaluation Examination and Testing Procedure
TM000019, Rev. R	Determination of Tensile/Elongation Properties of Elastomeric Materials
TM000401, Rev. C	Determination of Joint Bond Strength
TM000406, Rev.	Tension Set
TM000366, Rev.	Gel Cohesion

Attachments

Attachment 1	Mentor Customer Field Experience Report (FER)
Attachment 2	Mentor Retrieval Program Data Record Form - Visual
Attachment 3	Mentor Retrieval Program Data Record Form – Physical
Attachment 4	Mentor Explanted Device Decontamination Instructions

Attachment 1

MENTOR Customer Field Experience Report (FER)

Telephone # 1-800-258-3487 Fax # 972-659-6687

Demographic Information

Patient Name _____ SS# _____
Date of Birth _____ Weight _____
Physician's Name _____ Customer# _____
Address _____
Phone # _____ Fax # _____

Complaint Information

Product Description (include size) _____

Device Left ❑ Right ❑	**Device** Left ❑ Right ❑
Complaint _____	Complaint _____
Catalog # _____ **Lot #** _____	**Catalog #** _____ **Lot #** _____
Date Problem Observed _____	Date Problem Observed _____
Capsular Contracture Yes❑ No❑ Grade_____	Capsular Contracture Yes❑ No❑ Grade___
Infection Yes❑ No❑	Infection Yes❑ No❑
Culture Result _____	Culture Result _____

Implant History

Date of Implant _____	Date of Implant _____
Indication: 1°Augmentation ❑ 1°Reconstruction ❑	Indication: 1°Augmentation ❑ 1°Reconstruction ❑
Revision Recon. ❑ Revision Augmentation ❑	Revision Recon. ❑ Revision Augmentation ❑
Placement Submuscular ❑ Subglandular ❑	Placement Submuscular ❑ Subglandular ❑
Incision Site _____	Incision Site _____
Incision Size _____	Incision Size _____
Final Fill Volume _____	Final Fill Volume _____
Fill Schedule _____	Fill Schedule _____
Betadine Usage Yes❑ No❑	Betadine Usage Yes❑ No❑
Soak Yes❑ No❑ Concentration _____	Soak Yes❑ No❑ Concentration _____
Pocket irrigation Yes❑ No❑ Conc. _____	Pocket irrigation Yes❑ No❑ Conc. _____
Intraluminal Use Yes❑ No❑ Conc. _____	Intraluminal use Yes❑ No❑ Conc. _____
Pocket rinsed Yes❑ No❑	Pocket rinsed Yes❑ No❑

Did the device come into contact with the patient? Yes ❑ No ❑
Is patient currently involved in any clinical studies? Yes ❑ No ❑ If yes, specify _____

Explant History

Date of Explant _____	Date of Explant _____
Fill Volume _____ (see below)	Fill Volume _____ (see below)
Capsular Contracture Yes❑ No❑ Grade___	Capsular Contracture Yes❑ No❑ Grade___
Infection Yes❑ No❑	Infection Yes❑ No❑
Culture Result _____	Culture Result _____
Reason for Explant _____	
Incision Site _____	Incision Site _____
Incision Size _____	Incision Size _____
Tissue ingrowth on shell observed Yes❑ No❑	Tissue ingrowth on shell observed Yes❑ No❑
Tissue ingrowth in valve observed Yes❑ No❑	Tissue ingrowth in valve observed Yes❑ No❑

Did the device(s) sustain any damage during explant? Yes ❑ No ❑

Attachment 1 (continued)

MENTOR Customer Field Experience Report (FER)

General Patient Information

Mammograms performed since implant Yes❑ No❑ If yes, indicate number _____
Breast massage employed Yes❑ No❑
Any history of breast trauma Yes❑ No❑ If yes, provide details: side (L or R), date and type of trauma
_____
Any other relevant information Yes❑ No❑ If yes, provide details
_____

Device Replacement Information

Catalog # of No Charge Replacement device(s) requested_____
Replacement device: (L) Cat #_____Lot#_____
(R) Cat #_____Lot #_____
Explan_____

Method of Decontamination _____ Date _____
Comments_____
_____

Provider of Information_____Title_____

Attachment 2

MENTOR RETRIEVAL PROGRAM
DATA RECORD FORM

VISUAL OBSERVATIONS

Date of evaluation_____ **PE Reference #** _____

L - Device Type _____ **Catalogue Number** _____ **L/N** _____
R - Device Type _____ **Catalogue Number** _____ **L/N** _____

Macroscopic- Left
General observations _____
Exposure conditions _____
Failure location _____
Failure dimensions _____
Color of Device _____
Failure Characteristics _____
Other _____
_____

Macroscopic- Right
General observations _____
Exposure conditions _____
Failure location _____
Failure dimensions _____
Color of Device _____
Failure Characteristics _____
Other _____
_____

Microscopic- Left
Surface Characteristics _____
Failure Characteristics _____
Fold Flaw Present _____
Other _____
_____

Microscopic- Left
Surface Characteristics _____
Failure Characteristics _____
Fold Flaw Present _____
Other _____
_____

Attachment 3

MENTOR RETRIEVAL PROGRAM
DATA RECORD FORM

PHYSICAL & MECHANICAL TESTING

Date of evaluation_____ **PE Reference #** _____

L - Device Type _____ **Catalogue Number** _____ **L/N** _____
R - Device Type _____ **Catalogue Number** _____ **L/N** _____

PHYSICAL ANALYSIS

Reference specification _____ **Reference document** _____

L- Weight _____ **Diameter** _____ **Projection** _____

R- Weight _____ **Diameter** _____ **Projection** _____

MECHANICAL ANALYSIS

Test Method	Results	Spec Range

OTHER ANALYSIS

Test Method	Results	Spec Range

If required, specify

_____

_____

Technician Signature/Date _____

Reviewer Signature/Date _____

Attachment 4

MENTOR EXPLANTED DEVICE DECONTAMINATION INSTRUCTIONS

Low Bleed Gel-Filled Devices:

1. Wrap the prosthesis in a suitable wrapping material intended for autoclave use. Place the unit in a clean, open autoclaving tray.

2. Autoclave by one of the following Gravity Displacement Decontamination methods:

Standard Cycle:	**30 minutes at 250° F (121° C) and 15 psi**
Optional Cycle:	**15 minutes at 270° F (132° C) and 30 psi**

Caution: Do not use a prevacuum high temperature autoclave cycle or an ethylene oxide sterilization cycle. Do not dry the implant using a vacuum Kyle.

LIQUID DISINFECTION INSTRUCTIONS

ALL Valve and Device Types:

Disinfection describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial endospores. This is generally accomplished by using a liquid chemical solution. Liquid chemical solutions may be used to achieve levels of disinfection which include sterilization, high-level disinfection, intermediate-level disinfection and low-level disinfection. [1]

High-Level Disinfection is expected to destroy all microorganisms, with the exception of high numbers of bacterial spores. This is the level of disinfection recommended for devices which cannot be sterilized by autoclaving. Glutaraldehyde is a dependable high-level disinfectant, when used according to manufacturer's instructions.[2]

1. Immerse the device in glutaraldehyde solution (e.g. CIDEX* Activated Dialdehyde Solution) per manufacturer's instructions. Device should be soaked for a period to time sufficient to achieve *high level disinfection.*

2. Remove the device from solution, rinse thoroughly and gently blot dry.

[1,2] Rutala WA APIC Guideline for selection and use of disinfectants AM J Infect Control 1990 58 100-101
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